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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
MARX, I

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/389,318

Applicant(s)

Suzuki et al.

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 28, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8, 10-15, and 17-32 is/are pending in the application.
- 4a) Of the above, claim(s) 8, 10-15, and 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 31, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

The amendment filed 2/28/01 is acknowledged.

To clarify the record it is requested that members of the genus *Mortierella*, subgenus *Mortierella*, be identified.

Applicant's election with traverse of Group I, claims 1, 3-7 and 31-32 in Paper No. 6 filed 2/28/01 is acknowledged. The traversal is over Groups I-III only. The traversal is on the ground(s) that because Groups I-III are classified in the same class and subclass, the "elected" subject matter would necessarily involve an overlapping search of the entire subject matter presently claimed.

However this is not found persuasive because the methods are of a different scope and the references which would be applied to one method would not necessarily anticipate or render obvious the other method.

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Note, for example that claim 8 requires a $\Delta 5$ denatures inhibitor. Burden in examining materially different groups having materially different issues also exists.

Further, it is doubted that applicants would readily accept the rejection of the process of the elected invention over a reference which related only to the process of Groups II or III.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 8, 10-15, and 17-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The rejection of claim 4 under 35 U.S.C. § 112, first and second paragraphs is overcome by the showing of the public availability of strains of *M. alliacea*.

The deposit rejection of claim 6, under 35 U.S.C. 112, first paragraph, is overcome by the Gardner declaration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 32 are substantial duplicates.

Claim 31 is vague and indefinite in that the medium wherein the member of *Mortierella* has the ability to produce about 7 g/l is not defined with sufficient specificity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, 6 and 31-32 are/remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kyle for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that Kyle discloses a maximum productivity of 5.3 g/L in 10 days of culturing. Yet all the invention as claimed requires is "the ability" to produce arachidonic acid of at least about 7 g/l. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent in their ability to produce arachidonic acid, from the strains discussed in the references.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1, 3-7 and 31-32 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that Kyle does not render the invention as claimed obvious because the reference discloses a maximum productivity of 5.3 g/L in 10 days of culturing and the reference does not disclose or suggest a process of production of arachidonic acid resulting in the production of at least 7 g/L. Yet, contrary to applicants' allegations, all the invention as claimed requires is **the ability** to produce arachidonic acid of at least about 7 g/l. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not the ability to produce arachidonic acid of applicants' cultured strains differs and, if so, to what extent in the ability of the strains discussed in the references.

In addition, and as noted in the last Office action, the only strain shown to have the required ability and, in fact, to produce the touted amount of arachidonic acid is the deposited strain SAM 2197(See, e.g., Table 1) using glucose as carbon source in conjunction with yeast extract and under specific process conditions.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re

Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Claims directed to the production and recovery of arachidonic acid by strain *Mortierella* SAM 2197 in amounts of at least 7 g/l in 5-10 days would be favorably considered.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Irene Marx
Primary Examiner
Art Unit 1651